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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,348	09/26/2001	Wolfram Steinhilber	24702	2818
20529	7590	02/02/2006	EXAMINER	
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			SCHNIZER, HOLLY G	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/889,348

Applicant(s)

STEINHILBER ET AL.

Examiner

Holly Schnizer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-13 and 15-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-29 is/are allowed.
- 6) ☒ Claim(s) 5,10,11 and 16 is/are rejected.
- 7) ☒ Claim(s) 6-9,12,13,15 and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/17/06 has been entered. No Amendments to the claims were filed with the RCE. Therefore, Claims 5-13 and 15-29 are pending and have been considered in this Office Action.

### ***Rejection Modified to Address Applicants arguments***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicants argue that while the Nicholson reference (the secondary reference used in the obviousness rejection in the previous Office Action) teaches storage stability of lyophilized products generally, it does not disclose lyophilization of protein products. Therefore, Applicants argue, there would be no motivation to modify Borron et al. with the teachings of the Nicholson reference. This argument has been considered but is not deemed persuasive in light of Borron in view of US Patent 6,267,958 which shows that it was well known in the art at the time of the invention that lyophilization could be used to increase stability of proteins.

Claims 5, 10, 11, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borron et al. (Am. J. Physiol. 275 (Lung Cell. Mol. Physiol. 19): L679-L686) in view of Nicholson (Dev. Biol. Stand. (1976) 36: 69-75).

As stated in the previous Office Actions, Borron et al. teach a composition comprising a purified recombinant SP-A that is lipid-free and contained in buffer (considered a carrier) at neutral pH (p. L680, Col. 2, last two paragraphs; indicates that recombinant SP-A was dialyzed against Tris buffer at pH 7.4). Also, as stated in the previous Office Action, the claims are drawn to a product with an intended use. However, without evidence that the intended use changes the product, the intended use is not considered because it is the product being claimed and not the method of using it.

The recombinant SP-A in the composition of Borron et al. appears to be indistinguishable from the recombinant SP-A obtainable by expression of a genomic sequence or by expression of a cDNA.

Borron et al. do not teach that the SP-A composition is in powder form.

The '958 patent teaches that the production of recombinant proteins for use pharmaceutically poses special problems due to their instability (see Col. 1, lines 18-40). The '958 patent teaches that freeze-drying is commonly used to enhance the stability of proteins during storage (see Col. 1, lines 41-50) and the patent is directed to improving the lyophilization process and thus stability of proteins formulations. The '958 patent teaches that the lyophilization will increase the stability of proteins generally and also provides some specific examples of proteins including lung surfactant proteins (Col. 6, line 54). The lyophilization process results in a powder form of a protein.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to lyophilize the SP-A solution of Borron et al. and create a composition in powder form, for increased stability during storage. Borron et al. indicates that the final preparation was stored (see p. L680, Col. 2, last sentence of "Recombinant SP-A"). One of ordinary skill in the art, with knowledge of both references, would have been motivated to lyophilize the Borron et al. composition since the '958 patent teaches that lyophilization will increase protein stability during the storage time.

### ***Claim Objections***

Claims 6-9, 12-13, 15, and 17 are objected to for depending from a rejected claim but would be allowable if rewritten in independent form including all of the limitations of the base claim.

### ***Conclusions***

Claims 5, 10, 11, and 16 are rejected. Claims 6-9, 12-13, 15, and 17 are objected to. Claims 18-29 are free of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Tuesday-Thursday from 10 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Holly Schnizer  
January 31, 2006